

**Notice of Allowability**

Application No.

09/775,262

Examiner

Lynda Jasmin

Applicant(s)

MCMENIMEN ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to November 23, 2004.
2. ☒ The allowed claim(s) is/are 1-5.
3. ☒ The drawings filed on 01 February 2001 and 21 January 2003 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
  - \* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☒ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Daniel Chapik on December 2, 2004.

2. The application has been amended as follows:

Claim 6 has been cancelled.

3. The following is an examiner's statement of reasons for allowance:

The closest prior art, Clynych (6,463,351 B1), discloses a method for producing customized medical device. A physician's computer system is equipped with custom computer software application, which permits images to be manipulated and modified with the assistance of a database of default manipulation. Clynych further discloses a device manufacturing facility that serves a plurality of scan facilities.

It is clear from the description of Linberg's invention that the prior art does not considered the possibility of "a medical device programmer in bi-directional telemetric data communication with and capable of programming one or more parameters of the at least one implantable medical device and the programmer is separately in communication a manufacturing control system to provide information to the medical

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device manufacturing control system about the at least one implanted medical device and to cause the manufacturing control system to initiate a build to order process to replace the at least one medical device in the inventory based on the information provided." This distinct feature has been added to the sole independent claim and renders it allowable.

The next closest prior art, Alt, (5,725,559), discloses an implantable medical device adapted to be upgradable at additional cost to allow a patient to receive the benefit of improved features or parameters of the device as needed by the patient.

It is clear from the description of Linberg's invention that the prior art does not considered the possibility of "the medical device programmer being separately in communication a manufacturing control system to provide information to the medical device manufacturing control system about the at least one implanted medical device and to cause the manufacturing control system to initiate a build to order process to replace the at least one medical device in the inventory based on the information provided." This distinct feature has been added to the sole independent claim and renders it allowable.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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4. The other prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

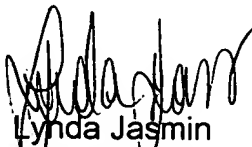
WO (01/56654 A1) discloses a medical device production where a programmer provides access to product information, specification to a manufacturing center.

Majlesein et al. discloses the need for sensor monitoring performance in quality products where just in time customized manufacturing needs dramatic adjustment in productivity.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynda Jasmin whose telephone number is (703) 305-0465. The examiner can normally be reached on Monday- Friday (8:00-5:30) alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert P Olszewski can be reached on (703) 308-5183. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

 12/6/04  
Lynda Jasmin  
Primary Examiner  
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